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Patent and Trademark Office
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Washington, D.C. 20231

SEP 17 1998

David L. Rose
Merck & Co., Inc.
P.O. Box 2000
Rahway, NJ 07065-0907

Re: Patent Term Extension
Application for
U.S. Patent No. 4,199,569

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Dear Mr. Rose:

An order granting an interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,199,569 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products).

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin

Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: STROMECTOL®
FDA Docket No.: 97E-0061

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE COMMISSIONER OF PATENTS AND TRADEMARKS

In re Merck & Co., Inc. :
Request for Patent Term Extension : ORDER GRANTING
U.S. Patent No. 4,199,569 : INTERIM EXTENSION

On January 8, 1997, Merck & Co., Inc., the owner of record in the Patent and Trademark Office (PTO) of U.S. Patent No. 4,199,569, filed an application for patent term extension under 35 U.S.C. § 156 based upon the regulatory review of the human drug product STROMECTOL® (ivermectin). The human drug product STROMECTOL® was approved for commercial marketing or use under section 505 of the Federal Food, Drug and Cosmetic Act by the Food and Drug Administration on November 22, 1996. The original term of the patent expired on October 3, 1997, but an interim extension under 35 U.S.C. § 156(e)(2) has been granted for a period of one year, i.e., until October 3, 1998. The patent claims the active ingredient ivermectin in the human drug product STROMECTOL® and a method of use of ivermectin. An extension of 1,026 days is requested.

PTO review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made by the Food and Drug Administration. Since the term of the patent, as already extended under 35 U.S.C. § 156(e)(2), would expire before a certificate of patent term extension can be issued, a second interim extension of the patent term is appropriate. The rights derived from an extension under 35 U.S.C. § 156(e), including an interim extension, are limited by 35 U.S.C. § 156(b).

A second interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,199,569 is granted for a period of one year from October 3, 1998, the expiration date of the patent, as extended by the prior one-year interim extension under 35 U.S.C. § 156(e)(2).

SEP 15 1998

Date



Bruce A. Lehman

Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks